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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO	
10/765,664	01/26/2004	Leonard S. Girsh	GIR-105CXC1	9812	
7550 0885,0508 SALIWANCHIK LLOYD & SALIWANCHIK A PROJESSIONAL ASSOCIATION PO BOX 142950 GAINESVILLE, FL 32614-2950			EXAM	EXAMINER	
			KAM, CHIH MIN		
			ART UNIT	PAPER NUMBER	
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			MAIL DATE	DELIVERY MODE	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## Application No. Applicant(s) 10/765,664 GIRSH, LEONARD S. Office Action Summary Art Unit Examiner CHIH-MIN KAM 1656 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 12 May 2008. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-8 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) \_\_\_\_\_ is/are allowed. 6) Claim(s) 1-8 is/are rejected. 7) Claim(s) \_\_\_\_\_ is/are objected to. 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some \* c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). \* See the attached detailed Office action for a list of the certified copies not received.

1) Notice of References Cited (PTO-892)

Paper No(s)/Mail Date 5/12/08

Notice of Draftsperson's Patent Drawing Review (PTO-948)
Notice of Draftsperson's Patent Drawing Review (PTO-948)
Notice of Draftsperson's Patent Drawing Review (PTO-948)

Attachment(s)

Interview Summary (PTO-413)
Paper No(s)/Mail Date. \_\_\_\_\_.

6) Other:

5) Notice of Informal Patent Application

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### DETAILED ACTION

### Status of the Claims

1. Claims 1-8 are pending.

Applicants' amendment filed May 12, 2008 is acknowledged. Applicants' response has been fully considered. Claims 1, 2 and 6-8 have been amended. Therefore, claims 1-8 are examined.

#### Abstract

A marked copy of abstract filed May 12, 2008 is acknowledged, however, a clean copy of the abstract has not been submitted. Please submit a clean copy of the abstract.

### Withdrawn Claim Objections

3. The previous objection to claims 2 and 7, regarding recitation of non-elected species, is withdrawn in view of applicants' amendment to the claims, and applicants' response at page 7 in the amendment filed May 12, 2008.

# Withdrawn Claim Rejections - 35 USC § 112

- 4. The previous rejection of claims 1-8 under 35 U.S.C. 112, first paragraph, written description, is withdrawn in view of applicants' amendment to the claim, and applicants' response at pages 7-8 in the amendment filed May 12, 2008.
- 5. The previous rejection of claims 1-8 under 35 U.S.C. 112, second paragraph, is withdrawn in view of applicants' amendment to the claim, and applicants' response at page 8 in the amendment filed May 12, 2008.

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### Withdrawn Claim Rejections - Obviousness Type Double Patenting

6. The previous rejection of claims 1-8 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of co-pending application 11/501,380 (based on the elected claims filed 11/30/07; US 2007/0037777), is withdrawn in view of applicants' submission of a terminal disclaimer, and applicant's response at page 8 in the amendment filed May 12, 2008.

7. The previous rejection of claims 1-8 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of co-pending application 11/073,514 (US 2005/073,514), is withdrawn in view of applicants' submission of a terminal disclaimer, and applicant's response at page 8 in the amendment filed May 12, 2008.

### New Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- Claims 1-4 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kose (US 2004/0156886, filed June 12, 2002).

Kose discloses a sheet-like patch agent safe for skin, where one or more of the skin beauty ingredients such as collagen, lecithin, amino acids, L-arginine, grape extract, vitamin E, garlic extract and others can be mixed and used (paragraph [0032]). Since the reference teaches the listed components including collagen, lecithin, amino acids, L-arginine, grape extract,

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vitamin E and garlic extract can be mixed and used as the agent for the skin, thus, at the time of invention was made, it would have been obvious to one of ordinary skill in the art that the agent disclosed by Kose results in the claimed composition (claims 1-4 and 6).

### New Claim Rejections-Obviousness Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fcd. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fcd. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 1-8 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 and 11-27 of copending application 10/868,697 (based on the amended claims filed 3/13/08). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-8 in the instant application disclose an anabolic composition comprising cartilage, chondroitin sulfate, hyaluronic acid or collagen in an amount to act as anti-neo-inflammatory agent; about 1 to 3 grams of at least one polar surface active lipid; a plurality of L-amino acids and glycine; a component of Polyoxyethylene Sorbitan Monooleate (TWEEN 80), Sorbitan monooleate (SPAN 80), grape seed extract, grape extract, or combinations thereof; and vitamin B12, vitamin E, selenium, zinc or combination thereof. This is obvious variation in view of claims 1-6 and 11-27 of the co-pending application which disclose an anabolic composition

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comprising at least one glycosaminoglycan, proteoglycan aggregate complex of hyaluronic acid, extracellular matrix compound; about 1 to 3 grams of at least one polar surface active lipid; a plurality of L-amino acids and glycine of about 9 to 25 grams in molar ratio of human tissue; a component of Polyoxyethylene Sorbitan Monooleate (TWEEN 80), Sorbitan monooleate (SPAN 80), grape seed extract, grape extract, or combinations thereof; and vitamin E, selenium, zinc or combination thereof. Both sets of claims are directed to an anabolic composition comprising at least one extracellular matrix compound; at least one polar surface active lipid; a plurality of amino acids; a component of one surfactant; and vitamin E, selenium, zinc or combination thereof. Thus, claims 1-8 of the present application and claims 1-6 and 11-27 in the co-pending application are obvious variations of an anabolic composition comprising an anabolic composition comprising at least one extracellular matrix compound; at least one polar surface active lipid; a plurality of amino acids; a component of one surfactant; and vitamin E, selenium, zinc or combination thereof.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

#### Conclusion

#### 10 No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Bragdon can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Chih-Min Kam/ Primary Examiner, Art Unit 1656

CMK August 22, 2008